

 <p style="text-align: center;">ADMINISTRATIVE POLICIES AND PROCEDURES State of Tennessee Department of Correction</p>	Index #: 114.02	Page 1 of 11
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	Distribution: A	
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Approved by: George M. Little		
Subject: RESEARCH PROJECTS		

- I. AUTHORITY: TCA 43-603, TCA 43-606, TCA 41-21-601, TCA 10-7-504, et. seq., and 28 CFR, Part 46, Protection of Human Subjects.
- II. PURPOSE: To support research activities undertaken by, for, or with the Tennessee Department of Correction (TDOC) that are designed to contribute to scientific knowledge. All research must conform to policies outlined in 28 CFR, Part 46, Protection of Human Subjects and any subsequent revisions or amendments.
- III. APPLICATION: To TDOC staff, inmates, privately managed facilities, and all persons proposing research activities within the Department.
- IV. DEFINITIONS:
 - A. Informed Consent: The voluntary agreement by an inmate or staff to be a subject of a research project after they receive the material facts regarding the nature, consequences, and risks.
 - B. Minimal Risk: The probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental or psychological examination of healthy persons.
 - C. Research: Any project, departmental or external in origin, which involves the following:
 1. Systematic investigation of issues related to inmates, departmental staff, or departmental business, and/or research development, testing and/or evaluation that is designed to develop or contribute to knowledge, and
 2. Is generalizable or can be applied to other similar populations.

Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. Some demonstration and service programs may include a research component.
- V. POLICY: The TDOC shall encourage, support, and engage in research activities which develop knowledge; assist in establishing departmental goals, objectives, and plans for the future; and/or contribute to a more effective, efficient, and economical operation of the Tennessee correctional system and its subsystems.

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VI. PROCEDURES:

- A. Minimization of risk and protection of the confidentiality of all subjects will be addressed through a review of all research proposals by TDOC's Institutional Review Board (IRB).
- B. Members of the Institutional Review Board (IRB) will be appointed by the Commissioner of Correction with the Chairperson being the Director of Policy, Planning, and Research (PPR).
 1. Members of the IRB of TDOC will reflect diversity of professional competence so that the acceptability of the proposed research may be assessed in terms of operational ability to provide requested support to researcher while meeting commitments and regulations, applicable law, and standards of professional conduct and practice. A permanent member of the IRB shall be a member of the Legal Section of the Department.
 2. Assistant Commissioners, Central Office Directors, and Wardens affected by any request to conduct research shall receive copies of the research proposal for review and participation in discussion when the proposal is reviewed by the IRB of TDOC. Relevant managers will be consulted during the completion of an expedited review or when a proposal is deemed exempt from IRB review.
- C. The Chairperson of the IRB of TDOC will:
 1. Serve as departmental liaison to researchers, university personnel, other interested persons, and TDOC staff who initiate/sponsor collaborative research initiatives.
 2. Assume responsibility for maintenance of and completion of the duties of the IRB to include monitoring the progress of approved research activities, maintaining a record of research activities conducted under the auspices of the Department and their status, and submitting a final recommendation for action to the Commissioner upon completion of the proposal review process. Recommendation options include:
 - a. Approve without qualification
 - b. Approve with qualifications
 - c. Disapprove
- D. No research will compromise the security and safety of staff, visitors, and the general public or day-to-day institutional operations. Research will subject participating inmates to no more than minimal risk or inconvenience.
- E. All research projects must comply with all current TDOC policies regarding privacy of information and will not override any law or rule that provides greater protection of privacy of information including Section 10-7-504, Tennessee Code Annotated.

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1. Any employee or inmate who is asked to directly participate in an approved research project, e.g. survey or tests, shall be given the opportunity to participate or to decline participation. No one shall be required to participate.
 2. Inmates/employees electing to participate shall sign the Research Standard Consent Form, CR-1976, or a similarly approved consent form if personally identifiable information will be captured; a copy shall be placed in his/her file.
 3. Consent may not be required when secondary data, e.g. information from offender files or computer system, are used and information obtained is recorded in a way that participants' identity cannot be determined, directly or indirectly through identifiers linked to the individuals. This determination will be made on a case-by-case basis.
- F. The use of inmates for medical, pharmaceutical, or cosmetic experiments is prohibited. This does not preclude treatment of an inmate based on his/her need for a specific medical treatment that is not generally available.
- G. Any request to use employees, inmates, inmates' records, or specimens for purposes of research in any facility or the Central Office of TDOC must be submitted to the Chairperson of the IRB of TDOC.
1. Written requests for permission to conduct scientific research are required; this requirement is applicable to requests generated from within TDOC, from external agencies, or from individuals.
 2. Research involving inmates, their records, or specimens may require a full IRB review, may be eligible for an expedited review, or may be exempt from IRB review depending upon the nature of the research, the level of confidentiality to which participants data will be held, and if the research has been approved by another entity's IRB. Other factors may be considered also.
 3. The request to conduct research must include the following items. All materials shall be typed, in double spaced format.
 4. A cover page that conforms to General Research Proposal, CR-1975, on the TDOC website. At a minimum, the following issues must be addressed:
 - a. Focus of research: dissertation, Masters thesis, demonstration
 - b. Project/Pilot Study, Faculty Project, or Other
 - c. Proposal title
 - d. Date of submission
 - e. Principal investigator
 - f. Address of principal investigator

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- g. Daytime phone number of principal investigator
 - h. e-mail address of principal investigator
 - i. Institutional affiliation (if applicable)
 - j. Faculty advisor (if applicable)
 - k. Advisor's mailing address (if applicable)
 - l. Advisor's campus phone number (if applicable)
 - m. Advisor's e-mail address (if applicable)
 - n. Former title of proposal if previously presented
 - o. Brief detail of previous TDOC – IRB review (to include dates and outcomes)
 - p. Notation if the research is new, an amendment, or an addendum
 - q. If principal investigator is an employee/former employee; inmate/former inmate; or volunteer/former volunteer of TDOC or private correction contractor in Tennessee
5. The proposal shall also contain a one-page abstract of the proposed research that includes the principal investigator, title and organization affiliation should be identified. A brief description of the study including objectives, design, and methods should be included. Informed consent and confidentiality of subjects should also be addressed.
 6. A one-page vitae for each investigator shall be submitted.
 7. The body of the proposal shall concisely describe the study to include:
 - a. Objectives, design, methodology, and examples of instruments
 - b. Review of relevant literature and citations
 - c. Sampling plan (e.g., sample size, selection strategy, and TDOC institutions of interest)
 - d. A timeline that details initiation and completion of the project with specific notation of major phases of the project
 - e. Expected involvement of TDOC staff and their participation/facilitation of the study shall be clearly described
 - f. Expected actions and/or involvement of the researcher

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- g. Acknowledgment that all persons who enter TDOC facilities must pass security verification is expected
8. Informed consent and confidentiality of subjects (whether staff or inmates) shall be addressed; a consent form that conforms to CR-1976 on the TDOC website should be included in the proposal. Each component of the form must be addressed; if the researcher believes consent is not applicable, this should be noted on the form. Required components of informed consent include:
- a. The principal investigator's name and contact information
 - b. The title of the proposal
 - c. A description of the study that acknowledges the study involves research
 - d. A description of the procedures used in the study including identification of any experimental procedures
 - e. The duration of the participant's involvement
 - f. A description of any foreseeable risks or discomfort to participants
 - g. A description of any benefits to participants
 - h. A statement that notes alternate procedures or course of treatment, if any, that might be advantageous to the participant
 - i. A statement describing the extent to which confidentiality of records identifying the participant will be maintained with specific reference to who will have access to personally identifiable information
 - j. A statement that acknowledges that participants will be referred to only by number in any publications or presentations
 - k. A statement that the participant is free to withdraw consent and to discontinue participation in the research/study at any time without penalty or loss of benefits to which the participant would otherwise be entitled
 - l. Acknowledgment that no compensation of money or goods will be made to participants
 - m. Signature of the participant and a witness and dates of signature that acknowledge the statement - "I understand the procedures to be used in this study and the possible risks involved. All my questions have been answered. I also understand that my rights and privacy will be maintained, and I freely and voluntarily choose to participate. I understand that I may withdraw at any time."

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- H. All requests to conduct research must be accompanied by written executive approval of the research proposal from the agency or institution wanting to conduct the research regardless of whether human subjects are involved in the research or not.
1. The letter should indicate if the proposed research has been approved or exempted from the agency's IRB. If exempted, an explanation of why the research was exempted must be clearly stated.
 2. Researchers are expected to adhere to the requirements approved by the agency or institution IRB.
 3. In some cases, final IRB approval of other agencies (university/college) may be contingent on TDOC's approval of the proposal; in this situation TDOC will work with the researcher so delays do not occur; however, documentation of final IRB approval must be supplied, on agency letterhead, before data collection can begin.
- I. An expedited review may be recommended by the Chairperson of the IRB when a research proposal poses no more than minimal risk for participants or when minor changes are requested in research approved in the prior 12 months. An expedited review may be completed by the Chairperson of the IRB or designee. If not approved through expedited review, the proposal will be subject to a complete IRB review.
- J. The Chairperson of the IRB or designee may exempt a study from IRB review under certain conditions as noted in 28 CFR, Part 46; however, additional protections for human subjects may be provided by State or local laws or regulations or departmental policy. The types of research that may qualify for an IRB review exemption include:
1. Research conducted in established or commonly accepted educational settings involving normal educational practices.
 2. Research involving the use of educational tests, survey or interview procedures or observation of public behavior if:
 - a. data are recorded in such a manner that subjects cannot be identified,
 - b. disclosure of a subjects' responses could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial status, employability, or reputation.
 3. Research involving survey or interview procedures when the respondent is an elected official or appointed public official or candidate for public office.
 4. Research involving the collection or study of existing data documents, records, pathological specimens or diagnostic specimens if the sources are publicly available or the subjects cannot be identified.

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5. Unless specifically required by statute, research and demonstration projects which are conducted by or subject to the approval of U.S. Department or Agency heads, and which are designed to study or evaluate:
 - a. Programs under the Social Security Act or other public benefit service programs
 - b. To study procedures for obtaining benefits or services of those programs
 - c. To study changes in or alternatives to those programs
 - d. To study changes in the methods or levels of payment for benefits or services

- K. The Chairperson of the IRB or his/her designee shall perform an initial review of research proposals and either advise the researchers of the need for further information or forward a complete proposal to IRB members for review. Initial review shall include:
 1. Determination that all required parts of the proposal are present and complete; only complete proposals will proceed to a formal review process,
 2. Assessment of the scientific soundness of the project
 3. Assessment of the potential value of the study to the Department and to the criminal justice field
 4. Verification of information presented by the researcher
 5. Notification of researcher of additional information needed to evaluate the project
 6. Ensure the protection of individual rights and assurances of informed consent are adequate
 7. Potential disruption of normal operations
 8. Need for additional security
 9. Potential danger to offender, staff, or researcher
 10. Any financial impact to participants or to the department
 11. Issues of special interest to the Department
 12. The timeline necessary for TDOC staff to accommodate the specifics of the proposal so activity may begin

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- L. Formal review by members of the IRB and managers in VI.(B) above shall include discussion of each item from the initial review of the proposal components noted in VI.(G) above and other relevant issues. Each shall recommend, in writing to the Chairperson of the IRB or designee that the proposal either be:
 - 1. Approved without qualification
 - 2. Approved with qualifications
 - 3. Disapproved
- M. No research project shall be approved without the prior approval of the affected manager(s). An affected manager's failure to respond within 30 days shall be interpreted as approval without qualifications.
- N. Prior to the approval of the Commissioner, no research activity/data collection shall begin.
 - 1. Researchers will be notified in writing by the IRB of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research. If disapproved, a statement of the reasons for the decision will be included in the letter and the researcher will be given the opportunity to respond in writing.
 - 2. Upon approval, research is expected to progress in conjunction with the timeline specified within the proposal. Projects that deviate significantly from the proposed timeline may be required to seek re-approval through the Chairperson of the IRB and/or TDOC officials. The Chairperson of the IRB will be the final arbiter of project timeliness.
 - 3. Once a proposal has been approved, any changes to the proposal (e.g. methods, sampling data collection instruments, forms, timelines, etc.), must be submitted to and approved by the Chairperson of the IRB as an amendment to the proposed research.
- O. All persons conducting research in the Department shall be responsible for abiding by all requirements as imposed by law, policy, or guidelines as set by the Department, the violation of which may lead to the discontinuance of the current study and/or future research projects, or subject the violator to civil or criminal penalties.
- P. Researchers must provide the Chairperson of the IRB with two copies of the final research report and one copy of other reports/articles pre-publication. All research data collected is subject to verification prior to publication. The Chairperson of the IRB is responsible for disseminating research reports to Departmental administrators affected by the research.

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VII. ACA STANDARDS: 4-4108 through 4-4113, and 4-4402.

VIII. EXPIRATION DATE: March 15, 2011.



**TENNESSEE DEPARTMENT OF CORRECTION
RESEARCH STANDARD CONSENT**

PRINCIPAL RESEARCHER: _____

TITLE OF PROPOSAL: _____

1. Indicated below are the (a) purpose of this study; (b) procedures to be followed; and, (c) approximate duration of this study:

2. Discomforts, inconveniences and/or risks that can be reasonably expected are:

3. The participant's rights, welfare, and privacy will be protected in the following manner:

- a. In signing this consent form, you have not waived any of your legal rights, nor have you released this institution/agency from liability for negligence.
- b. All data obtained from you during the course of this study will be accessible only to the principal researcher(s) and

- c. Should the results of this project be published, you will be referred to only by number.

NOTE: YOU ARE FREE TO WITHDRAW THIS CONSENT AND TO DISCONTINUE PARTICIPATION IN THIS STUDY OR ACTIVITY AT ANY TIME.

4. This consent information was presented in (a) written ☐, or (b) oral ☐ form.

I understand the procedures to be used in this study and the possible risks involved. All my questions have been answered. I also understand that my rights and privacy will be maintained, and I freely and voluntarily choose to participate. I understand that I may withdraw at any time. I further understand that I will derive no benefit from participation in the study; no compensation will be earned, no reduction of sentence or special consideration will occur on my behalf for participation.

Date

Signature of Participant

Date

Signature of Witness



**TENNESSEE DEPARTMENT OF CORRECTION
GENERAL RESEARCH PROPOSAL**

- | | |
|--|---|
| <input type="checkbox"/> Dissertation Research
<input type="checkbox"/> Masters Thesis Research
<input type="checkbox"/> Demonstration Project/Pilot Study | <input type="checkbox"/> Faculty Research
<input type="checkbox"/> Other |
|--|---|

IDENTIFICATION INFORMATION: (Complete all items. Use "N/A" if necessary.)

1. Title of Proposal: _____
2. Date: _____
3. Principal Researcher: _____
4. Address: _____

5. Phone Number: _____
6. E-mail Address: _____
7. Is principal researcher: a) current / former employee of TDOC, or private contractor _____
 b) inmate / former inmate _____
 c) volunteer / former volunteer of TDOC or private contractor _____
8. Faculty Advisor: _____
9. College or University: _____
10. Advisor's Campus Box Number _____ Phone Number: _____
11. Advisor's E-mail Address: _____
12. Former Title of Proposal (if applicable): _____
13. Identify any other previous committee reviews, dates, and results: _____

14. This proposal is: ☐ New ☐ An Amendment ☐ An Addendum
15. Include a research proposal including the following:
 - a) purpose of the study
 - b) procedures to be followed
 - c) approximate duration of the study
 - d) any discomforts, inconveniences, and/or risks that can be reasonably expected